

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

PROSPECT DCMH LLC, dba,
DELAWARE COUNTY MEMORIAL
HOSPITAL,

Plaintiff,

v.

XAVIER BECERRA, Secretary,
United States Department of Health
and Human Services,

Defendant.

Case No.: 2:24-cv-04678-PD

**PLAINTIFF'S COMBINED MEMORANDUM OF POINTS AND
AUTHORITIES IN OPPOSITION TO SECRETARY'S MOTION TO
DISMISS AND IN SUPPORT OF PLAINTIFF'S MOTION FOR
SUMMARY JUDGMENT**

TABLE OF CONTENTS

	<u>Page</u>
I. INTRODUCTION	1
II. THE CONTROLLING MEDICARE PRINCIPLES	3
A. The Applicable Medicare Statutes	3
B. The Applicable Medicare Regulations	4
C. “Deactivation” of Medicare Billing Privileges	5
III. THE FACTS	6
IV. OPPOSITION TO MOTION TO DISMISS	10
A. Standard of Review	10
B. DCMH Has Standing to Seek This Court’s Review of Novitas’ Decisions.	10
C. This Court Has Subject Matter Jurisdiction over This Matter.	11
V. DCMH IS ENTITLED TO SUMMARY JUDGMENT.....	15
A. Standard of Review	15
B. The Medicare Statutes Do Not Authorize and Thus Do Not Allow MACs to Terminate a Provider’s Medicare Agreement.	16
C. The Medicare Statutes Do Not Permit MACs to Deactivate a Provider’s Medicare Billing Privileges.	18
D. The Medicare Statute Does Not Authorize Terminations Based on the “Cessation of Business.”	19
E. DCMH Did Not Voluntarily Terminate Its Provider Agreement.	20
F. The Medicare Statute Expressly Prohibits the Retroactive Termination of a Medicare Provider Agreement or Enrollment.	22
G. The Retroactive Implementation of the Termination and Deactivation Violates DCMH’s Due Process Rights.	23
VI. CONCLUSION AND REMEDIES REQUIRED	25

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Agendia, Inc. v. Becerra</i> , 4 F.4th 896 (9th Cir. 2021)	18
<i>American Bus Assn. v. Slater</i> , 231 F.3d 1 (D.C. Cir. 2000)	20
<i>In re BR Healthcare Sols., LLC</i> , 2021 WL 4597761 (W.D. Tx. Oct. 5, 2021)	21
<i>D & G Holdings, L.L.C. v. Becerra</i> , 22 F.4th 470 (5th Cir. 2022)	13, 16
<i>Hays v. Leavitt</i> , 583 F. Supp. 2d 62 (D.D.C. 2008), <i>aff’d sub nom.</i> <i>Hays v. Sebelius</i> , 589 F.3d 1279 (D.C. Cir. 2009)	15
<i>Hays v. Sebelius</i> , 589 F.3d 1279 (D.C. Cir. 2009)	17
<i>Jones and Manzi v. CVS Health Corp.</i> , No. 24-cv-1703, 2024 WL 4643514 (E.D. Pa. Oct. 31, 2024)	12
<i>Kaiser v. Blue Cross of Cal.</i> , 2006 WL 8448799 (D. Idaho, Sept. 22, 2006)	21
<i>Lake Region Healthcare Corp. v. Becerra</i> , 113 F.4th 1002 (D.C. Cir. 2024)	15, 16
<i>Loper Bright Enterprises v. Raimondo</i> , 144 S. Ct. 2244 (2024)	16
<i>Louisiana Pub. Serv. Comm’n v. F.C.C.</i> , 476 U.S. 355 (1986)	16
<i>In re MCP No. 185</i> , ___ F.6th ___, 2025 WL 16388 (6th Cir. Jan. 2, 2025)	16

TABLE OF AUTHORITIES**Page(s)****Cases (*con't*)**

<i>Nassau Nursing Home v. Heckler</i> , 614 F. Supp. 1091 (E.D.N.Y. 1985)	24
<i>Parkview Adventist Medical Center v. United States</i> , 2:15-cv-00320, 2016 WL 3029947 (D. Me. May 25, 2016)	13, 14, 20
<i>Restaurant Law Center v. United States Dep't of Labor</i> , 120 F.4th 163 (5th Cir., 2024)	16
<i>Santiago v. Leavitt</i> , 2008 WL 4131524 (N.D. Tx. Sept. 3, 2008)	21
<i>Senior Life York, Inc. v. Azar</i> , 418 F. Supp. 3d 62 (M.D. Pa. 2019)	13, 25
<i>Shalala v. Ill. Council on Long Term Care</i> , 529 U.S. 1 (2000)	12
<i>Temple University Hospital, Inc. v. Secretary United States Dep't of Health and Human Servs.</i> , 2 F.4th 121 (3d Cir. 2021)	11, 12, 14
<i>U.S. Telecom Ass'n v. F.C.C.</i> , 359 F.3d 554 (D.C. Cir. 2004)	17
<i>Utah v. Su</i> , 109 F.4th 313 (5th Cir. 2024)	16

Statutes

5 U.S.C.	
§ 558(b)	20
§ 706	15
§ 706(2)(B)	15, 25
§ 706(2)(C)	15, 25
§ 706(2)(D)	15, 25

TABLE OF AUTHORITIES

Page(s)

Statutes (*con't*)

28 U.S.C.	
§ 1331.....	3
§ 1361.....	3, 14
42 U.S.C.	
§ 405(b).....	4
§ 1320a-7(c).....	4, 22
§ 1320a-7(c)(1)	4
§ 1320a-7(c)(2)	4
§ 1395.....	3
§§ 1395c – 1395i.....	3
§ 1395cc	4, 15
§ 1395cc(b)	17, 19
§ 1395cc(b)(1).....	3, 4, 22
§ 1395cc(b)(2).....	3
§ 1395cc(b)(2).....	3
§ 1395cc(b)(3).....	3, 22
§ 1395cc(h)	4, 24
§§ 1395j-u	3
§ 1395kk-1(a)(4)	3, 18
§ 1395u(a).....	3

Regulations and Rules

42 C.F.R.	
§ 405.498.....	24
§ 405.800(b).....	6
§ 422.756(b).....	25
§ 424.540.....	6, 18
§ 424.540(a)(7)	6, 8, 18
§ 424.540(c)	6
§ 424.540(d)(1)(ii)(D).....	6
§ 424.545(b).....	6, 7
§ 424.546(a)	6
§ 489.....	4

TABLE OF AUTHORITIES**Page(s)****Regulations and Rules (*con't*)**

42 C.F.R.

§ 489.1(b).....	4
§ 489.52.....	5
§ 489.52(a)(1)	4, 22
§ 489.52(b).....	4
§ 489.52(b).....	22
§ 489.52(b)(3)	20
§ 489.53.....	5
§ 489.53(a)	5
§ 489.53(d).....	5
§ 498.3(b).....	6
§ 498.3(b)(8)	5
§ 498.3(b)(17)	5, 6

86 Fed. Reg. 62240 [November 9, 2021]	19
---	----

86 Fed. Reg. 62359 [November 9, 2021]	19
---	----

Federal Rules of Civil Procedure

Rule 12(b)(1).....	10
Rule 56.....	15
Rule 56(c).....	10

I. INTRODUCTION

As explained below, the controlling Medicare statutes and due process of the law protect providers of Medicare services, such as plaintiff Prospect DCMH, LLC dba Delaware County Memorial Hospital (“DCMH”), from being summarily terminated from the Medicare program. This is especially true with respect to retroactively-imposed terminations, such as that applied to DCMH in this matter.

Yet, in complete disregard of these constitutional and statutory mandates, and without affording DCMH any prior notice, on May 21, **2024**, a Medicare Administrative Contractor (“MAC”), Novitas Solutions (“Novitas”), summarily terminated DCMH’s Medicare provider agreement and enrollment and deactivated its Medicare billing privileges effective November 7, 2022.

Despite the current efforts of the Secretary of Health and Human Services (“Secretary”) to rewrite the history surrounding this situation, DCMH did not voluntarily cease providing inpatient services on November 7, 2022, as wrongly concluded by Novitas. Rather, effective that date, November 7, 2022, the Pennsylvania Department of Health (“PA DOH”) expressly prohibited DCMH from admitting inpatients (but not outpatients) to its hospital. Yet, hoping to provide after-the-fact support for Novitas’ May 21, 2024 decision, the Secretary repeatedly insists that DCMH “voluntarily” terminated its Medicare participation effective November 7, 2022.

While Novitas afforded DCMH a post-termination opportunity to respond in writing to its erroneous decision, Novitas rubber-stamped its May 21, 2024 determination on July 1, 2024. And, in violation of due process and in disregard of the controlling Medicare administrative appeal requirements, neither Novitas nor the Secretary furnished DCMH with any further administrative appeal rights, leaving DCMH with no choice but to pursue this court action.

The Secretary has responded by filing a motion to dismiss DCMH's complaint on ill-reasoned standing and jurisdictional arguments. And to support its "motion to dismiss," he presents prolix exhibits consisting of media reports and other inadmissible and extra-record evidence. The Secretary apparently hopes the Court will decide de novo that DCMH voluntarily ceased operating and providing hospital services to inpatients on November 7, 2022.

According to the Secretary, DCMH lacks standing to bring this action because it has suffered no actual or legal injury, thus depriving this Court of jurisdiction. Alternatively, the Secretary contends the Court lacks subject matter jurisdiction because DCMH has failed to prove that Congress has waived sovereign immunity.

The opposite is true, however. Based on the undisputed material facts and the controlling legal principles, Novitas' determination has caused legal and actual injury to DCMH, which this Court has the authority to remedy under the Medicare

Act and/or 28 U.S.C. §§ 1331 and 1361, pursuant to DCMH's motion for summary judgment.

II. THE CONTROLLING MEDICARE PRINCIPLES

A. The Applicable Medicare Statutes

Medicare, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, is the federal healthcare program for the aged and disabled. Part A of the program covers inpatient hospital services. 42 U.S.C. §§ 1395c – 1395i. Part B of the program covers, among other services, outpatient hospital services. 42 U.S.C. §§ 1395j-u. Both Part A and Part B hospital services are affected by Novitas' decisions in this case, because DCMH, like most hospitals, furnished inpatient and outpatient services to Medicare beneficiaries during the period at issue.

Congress has authorized the Secretary, through the Centers for Medicare & Medicaid Services ("CMS,"), a government agency, to contract with private entities, MACs, to administer Medicare "payment functions." 42 U.S.C. §§ 1395kk-1(a)(4), 1395u(a). These statutes do **not** authorize the functions exercised by Novitas in this case. Indeed, the statute controlling the termination of provider agreements, 42 U.S.C. § 1395cc(b)(1) – (b)(3), makes no reference to MACs playing any role in the termination process. Instead, the statute expressly places such responsibility on "the Secretary." For example, Section 1395cc(b)(2) specifies that the Secretary may terminate a provider agreement. And, Section

1395cc(b)(3) expressly requires that a termination of such an agreement “shall become effective on the same date and in the same manner” as an exclusion from Medicare participation under 42 U.S.C. §1320a-7(c). Under this latter provision, subsections (c)(1) and (c)(2), an exclusion becomes effective only **after** the Secretary notifies a provider it is being excluded and only affects payment for services furnished thereafter.

Section 1395cc(h) gives institutions dissatisfied with the Secretary’s decision to terminate a provider agreement the right to a hearing to the same extent as provided in 42 U.S.C. § 405(b). Judicial review is also available after such a hearing is provided. These rights were not afforded DCMH here.

B. The Applicable Medicare Regulations

At 42 C.F.R. § 489.1(b), the Secretary identifies Section 1866 of the Social Security Act (codified at 42 U.S.C. § 1395cc) as the basis for actions affecting Medicare provider agreements. This regulation and others in Part 489 make no reference to MACs. However, the regulation does mention CMS’ role in the process.

Consistent with the controlling statute, 42 U.S.C. § 1395cc(b)(1), the regulation at 42 C.F.R. § 489.52(a)(1), allows a provider to terminate its agreement with the Secretary by giving CMS notice of such termination. But, the regulation at subsection (b) specifies that a “cessation of business” is deemed to be a

termination by the provider, effective with the date the provider “stopped providing services to the community.” Significantly, however, this regulatory provision is **not set forth** in the controlling Medicare statutes.

CMS is also authorized by regulation to terminate a provider agreement under various circumstances. 42 C.F.R. § 489.53(a). Yet, subsection (d) of this regulation requires that CMS give the provider advance notice of such termination. Neither 42 C.F.R. § 489.52 nor 42 C.F.R. § 489.53 discusses any role for a MAC in the termination processes. Indeed, Sections 489.52 and 489.53 speak only of CMS acting for the Secretary concerning terminations of provider agreements.¹

Sections 498.3(b)(8) and (17) expressly consider the termination of a provider agreement and/or termination of enrollment in Medicare to be an “initial determination” subject to additional appeal rights and judicial review. As discussed below, Novitas did not inform or provide DCMH with these rights even though Novitas terminated DCMH’s Medicare participation.

C. **“Deactivation” of Medicare Billing Privileges**

The Medicare statutes do not address or authorize the “deactivation” of Medicare billing privileges. However, such deactivation of a provider’s Medicare

¹ The Secretary is left with arguing in his brief (Doc. 12, page 26) that CMS, and not Novitas, actually issued the two decisions because the first page of Novitas’ stationery includes the acronym “CMS.” However, the undisputed fact is that the two decisions are signed by Novitas’ employees, not CMS employees.

billing privileges is addressed in the Medicare regulations at 42 C.F.R. § 424.540.

Under newly added subsection (a)(7) of this regulation, “CMS” may deactivate billing privileges if the provider “is voluntarily withdrawing from Medicare.”

And, a “deactivation” may be imposed as of the date the provider voluntarily withdrew from the Medicare program. 42 C.F.R. § 424.540(d)(1)(ii)(D).

Importantly, deactivation of Medicare billing privileges is not supposed to “have any effect on a provider’s . . . participation agreement.” 42 C.F.R. § 424.540(c).

The only process for challenging a deactivation of billing privileges decision under the regulations is the right to submit a “rebuttal to CMS” under 42 C.F.R.

§§ 424.545(b) and 424.546(a).²

III. THE FACTS

By letter dated May 21, 2024, Novitas informed DCMH that its Medicare “provider agreement has been terminated and your enrollment in the Medicare program has been voluntarily terminated effective” November 7, 2022. In this

² A deactivation is different from a “revocation” of Medicare billing privileges. Only a written rebuttal is available to a provider who “receives written notice from CMS or its contractor” that privileges are to be or have been deactivated. The rebuttal decision regarding the deactivation of billing privileges is not “an initial determination” under 42 C.F.R. § 498.3(b), which effectively precluded DCMH from accessing further administrative appeal steps. “Revocations” of billing privileges, however, do trigger formal appeal rights under 42 C.F.R. §§ 405.800(b) and 498.3(b)(17).

same notice, Novitas informed DCMH that its Medicare billing privileges were being “deactivated” effective this same date, November 7, 2022. Novitas listed “CEASED OPERATIONS” as the reason for these actions. Statement of Undisputed Facts (“Statement”), para. 4.

In this same letter, Novitas informed DCMH of its “REBUTTAL RIGHTS” to challenge the deactivation under 42 C.F.R. § 424.545(b) if it believed the “deactivation determination is not correct.” Novitas further stated that DCMH “may only submit one rebuttal in response to this deactivation of your Medicare enrollment.” The letter provided no notice of any right to any other administrative appeal process. Statement, para. 5.³

By letter dated June 4, 2024, DCMH’s legal representative filed DCMH’s rebuttal statement disagreeing with the termination of DCMH’s provider agreement and deactivation of its billing privileges “because DCMH did not voluntarily terminate its provider agreement, contrary to what was stated in the May 21 letter.” DCMH’s rebuttal explains in detail the factual basis for this position, supported by documentation, including DCMH’s September 21, 2022 letter providing PA DOH with updated information regarding DCMH’s intention

³ Novitas is a MAC, which has contracted with CMS, a governmental sub-agency of Health and Human Services. Novitas is a private company and not a part of CMS or any other governmental entity. Statement, para. 6.

to eventually merge into Crozer Chester Medical Center, which would cause a “temporary pause in certain operations,” at DCMH. Statement, para. 7.

In an October 7, 2022 email, Garrison Gladfelter, the Chief of PA DOH’s Division of Acute and Ambulatory Care and the recipient of the September 21, 2022 letter, characterized DCMH’s “temporary pause” as a “temporary stop,” as opposed to ceasing operations. Statement, para. 8.

In response to DCMH’s June 4, 2024 rebuttal, Novitas issued a “Rebuttal Determination” on July 1, 2024. The Determination consists primarily of a repetition of DCMH’s rebuttal contentions without responses and concludes that “as a result of the provider agreement being terminated, Novitas Solutions finds that the deactivation of Medicare billing privileges under 42 C.F.R. §424.540(a)(7) was justified.” Once again, Novitas gave DCMH no notice of any further administrative appeal rights. Statement, para. 9.

The November 7, 2022 effective date of Novitas’ May 21, 2024, and July 1, 2024 adverse decisions reflects the November 7, 2022 effective date of PA DOH’s November 4, 2022 order suspending DCMH’s emergency services and imposing a ban on admissions at DCMH due to “deficiencies” that “pose a significant threat to the health and safety of patients.” Statement, para. 10.

DCMH submitted various “plans of corrections” to State DOH to address the alleged deficiencies, including plans submitted in 2022 and March 2023. On May

17, **2024**, State DOH informed DCMH that it was rejecting DCMH's most recent plans of corrections and was denying the request for an approval of the merger plan proposed in 2022 based primarily on PA DOH's November 2022 order. Statement, para. 11. DCMH's state license remained in effect until November 12, 2024, two years after the November 7, 2022 Medicare termination. Statement, para. 14.

DCMH continued to furnish medically necessary services, such as radiology oncology services, imaging services, cyberknife services and surgery to DCMH "outpatients," including Medicare beneficiaries, following PA DOH's imposition of sanctions in November 2022. PA DOH's November 4, 2022 order did not affect DCMH's ability and right to do so. No one, including CMS and Novitas, gave DCMH any notice prior to its receipt of Novitas' May 21, 2024 letter that its Medicare provider agreement, enrollment, and billing privileges were going to be terminated or deactivated. And, certainly no one indicated that such action was going to be implemented retroactively. DCMH did not intend to voluntarily or otherwise terminate DCMH's enrollment in Medicare in November 2022 or at any other time prior to Novitas' May 21, 2024 decision. DCMH's plan to merge with another Prospect entity was intended to proceed in a manner that would have preserved DCMH's ability and right to continue to bill for its services throughout the transition and merger. Statement, para. 12.

If the retroactive termination is permitted to be implemented retroactively as upheld by Novitas on July 1, 2024, not only will DCMH be at risk for recoupment/repayment of millions of dollars, but it will also be unable to proceed with a sale of the hospital to a non-profit organization. Statement, para. 13.

IV. OPPOSITION TO MOTION TO DISMISS

A. Standard of Review

DCMH agrees with the Secretary that the jurisdiction issue may be addressed in a motion filed under Fed. R. Civ. Proc. 12(b)(1). DCMH further agrees that the Court may go beyond the allegations in the complaint in determining whether to grant a motion to dismiss under Fed. R. Civ. Proc. 12(b)(1).

However, the evidence presented to the Court in the motion to dismiss must be admissible as with other motions, including summary judgment motions under Fed. R. Civ. Proc. 56(c). Here, the Secretary submits no declaration or affidavit laying a foundation for any of the “evidence” on which he relies. And, much of the “evidence” consists of various layers of hearsay and other inadmissible submissions, including media articles and photographs from Google maps, as well as legal arguments.

B. DCMH Has Standing to Seek This Court’s Review of Novitas’ Decisions.

The Secretary contends that DCMH suffered no injury as a result of Novitas' May and July 2024 decisions terminating it from the Medicare program and deactivating its Medicare billing privileges retroactively to November 7, 2022. Indeed, the Secretary goes so far as to assert that DCMH will suffer no financial injury as a result of the retroactive actions even though the Secretary knows that the retroactive decision will cause Medicare to disallow millions of dollars in previous Medicare payments to DCMH. In fact, on January 2, 2025, Novitas issued a "Provider Payment Summary Report" showing a \$3 million reduction in the amount paid to DCMH due to the retroactive termination and deactivation of billing privileges. Statement, para. 15.

Moreover, contrary to the Secretary's arguments, DCMH has been denied due process and continues to be deprived of its "concrete" rights as a Medicare provider under the controlling Medicare statutes, as explained *infra*. These deprivations are directly traceable to Novitas, the Secretary's agent. And, they **are not** "self-inflicted," as suggested by the Secretary.

C. This Court Has Subject Matter Jurisdiction over This Matter.

DCMH is aware of its obligation to establish this Court's subject matter jurisdiction over this Medicare dispute. *See Temple University Hospital, Inc. v. Secretary United States Dep't of Health and Human Servs.*, 2 F.4th 121, 130 (3d Cir. 2021) ("*Temple*") (although the Secretary failed to raise the subject matter

jurisdiction issue in the district court, the issue was not “waived,” and the Court concluded that it lacked jurisdiction because of the channeling requirements of the Medicare Act and other circumstances).

Here, however, unlike in *Temple*, if this Court does not assert jurisdiction, there will be no judicial review of Novitas’ decisions. In short, DCMH is not skipping administrative appeal steps. To the contrary, under the circumstances of this case, DCMH was provided only one chance to challenge the Novitas’ May 21 and July 1, 2024 decisions – the right to submit a written rebuttal statement to Novitas, which DCMH did. Neither Novitas nor CMS provided DCMH with any further administrative review rights.

As the court in *Temple* acknowledged, 2 F.4th at 131, in *Shalala v. Ill. Council on Long Term Care*, 529 U.S. 1, 19 (2000), when the channeling requirement would not simply channel review through the agency, but would mean “no review at all,” an exception must be made to allow judicial review under federal question jurisdiction. Based on Novitas’ actions and inactions, DCMH has no basis for further administrative review under the Medicare appeals process. In such a situation, the channeling requirement of the Medicare Act is not applicable. *See Jones and Manzi v. CVS Health Corp.*, No. 24-cv-1703, 2024 WL 4643514, at *6 (E.D. Pa. Oct. 31, 2024) (court rejects application of channeling requirement because there was no statutory ground under the Medicare program to challenge

the exclusion of generics from the Medicare formulary in administrative review).
See also D & G Holdings, L.L.C. v. Becerra, 22 F.4th 470, 477 (5th Cir. 2022)
 (where Medicare statute and regulations do not allow further review because of the
 lack of an “initial determination,” jurisdiction is appropriate due to the “strong
 presumption that Congress intends judicial review of administrative action”).

This Court should also not delay review of the purely legal issues presented
 for review for other reasons. The due process and *ultra vires* challenges to
 Novitas’ determinations are procedural challenges that are collateral to the
 substantive merits of the issue of whether there is a basis to impose a retroactive
 termination of DCMH’s Medicare provider agreement and enrollment and whether
 there is a basis for deactivating DCMH’s billing privileges retroactively. *See*
Senior Life York, Inc. v. Azar, 418 F. Supp. 3d 62, 71-73 (M.D. Pa. 2019) (court
 asserts jurisdiction to determine whether entity could challenge Secretary’s
 decision on procedural due process grounds among others).

Significantly, in his discussion of “Federal Jurisdiction” (Doc. 12, pages 32-
 35), the Secretary basically ignores **Medicare** cases on jurisdiction, including
 those discussed above. Instead, he relies heavily on inapplicable, non-Medicare
 cases pertaining to the doctrine of sovereign immunity. And, in the one Medicare
 case the Secretary does discuss, *Parkview Adventist Medical Center v. United*
States, 2:15-cv-00320, 2016 WL 3029947 (D. Me. May 25, 2016) (“*Parkview*”),

the bankruptcy court required exhaustion of the Medicare appeal process that had been actually afforded to the provider, which is not the case here. Moreover, unlike the Secretary's position here, in *Parkview*, at page *3, the Secretary's Administrative Law Judge held that where a hospital is no longer providing inpatient hospital services but only outpatient services (as here), the resulting termination of the hospital must be deemed to be an "involuntary termination," which triggers administrative appeal rights not given to DCMH here. And, because such a situation must be deemed to have been an "involuntary termination," the Secretary was required to have given notice to the provider **at least 15 days before the termination could take effect.** DCMH is making this same argument here.

Finally, if this Court were to reject other bases of jurisdiction, it nevertheless should assert mandamus jurisdiction under 28 U.S.C. § 1361. *Temple*, 2 F.4th at 132, because, as shown below, there is a clear and indisputable right to relief, the Secretary is violating a clear duty, and no alternative remedy would arguably exist if mandamus relief were not afforded to DCMH. And, unlike in *Temple*, DCMH did, in fact, present its challenge to Novitas' determinations through the rebuttal process.

Thus, at a minimum, the Court should deny the Secretary's motion to dismiss.

V. DCMH IS ENTITLED TO SUMMARY JUDGMENT

A. Standard of Review

Summary judgment is an appropriate procedure for resolving a challenge to federal agency action, including actions against the Secretary in Medicare disputes. However, courts do not employ the standard of review set forth in Federal Rule of Civil Procedure 56 in such cases. Instead, the standard of review is prescribed by the relevant statute, here 42 U.S.C. § 1395cc, and the Administrative Procedure Act, 5 U.S.C. § 706. *See Hays v. Leavitt*, 583 F. Supp. 2d 62, 65 n.2 (D.D.C. 2008), *aff'd sub nom. Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009) (court grants summary judgment in favor of Medicare beneficiary because the Secretary's denial of benefits was not consistent with the controlling Medicare Statute).

The standard for judicial review of actions affecting Medicare payments to providers depends in large part on whether the subjects of such review are legal or factual issues. In *Lake Region Healthcare Corp. v. Becerra*, 113 F.4th 1002, 1007 (D.C. Cir. 2024), the court held that such review is measured by the provisions of the Administrative Procedure Act, 5 U.S.C. § 706. Sections 706(2)(B)(C) and (D), in turn, require the reviewing court to hold unlawful and set aside agency action found to be in excess of constitutional right, statutory jurisdiction, authority, limitations, or short of statutory right, or without observance of procedure required by law.

Importantly, in *Lake Region*, 113 F.4th at 1007, the court confirmed that reviewing courts must now independently “decide all relevant questions of law,” citing the Supreme Court’s landmark decision in *Loper Bright Enterprises v. Raimondo*, 144 S. Ct. 2244 (2024). No longer must the courts give the Secretary’s interpretation of ambiguous Medicare statutes *Chevron* deference. Rather, no matter how “impenetrable” or complex a statute might be, the statute must have a “single, best meaning,” which the reviewing court must determine and apply in a particular case. *Id.* at 2266.

Loper “upended” the “legal landscape” by overruling *Chevron*. See *Utah v. Su*, 109 F.4th 313, 318 (5th Cir. 2024) and *Restaurant Law Center v. United States Dep’t of Labor*, 120 F.4th 163, 170-71 (5th Cir. , 2024) (*Loper* requires reviewing courts to “use every tool at their disposal to determine the best reading of the statute and [to] resolve [any] ambiguity.”). See also *In re MCP No. 185*, __ F.6th __, 2025 WL 16388 (6th Cir. Jan. 2, 2025) (similar).

B. The Medicare Statutes Do Not Authorize and Thus Do Not Allow MACs to Terminate a Provider’s Medicare Agreement.

An administrative agency only possesses those powers expressly and specifically delegated to it by Congress. See *Louisiana Pub. Serv. Comm’n v. F.C.C.*, 476 U.S. 355, 374 (1986) (“[A]n agency literally has no power to act . . . unless and until Congress confers power upon it.”). See also *D&G Holdings*,

L.L.C. v. Becerra, *supra*, 22 F.4th at 477 (MAC’s attempted reopening of recoupment “effectuation” is *ultra vires* because there is no statutory authority allowing it to do so) and *Hays v. Sebelius*, *supra*, 589 F.3d at 1282-83 (MAC’s policy of limiting Medicare coverage to “the least costly alternative” was void because it was not authorized by the Medicare statute). This principle applies with full force here.

The Medicare statute applicable to the termination of a provider’s Medicare agreement and enrollment is 42 U.S.C. § 1395cc(b). This provision applies both to (1) situations where a provider voluntarily terminates a Medicare agreement, and (2) situations where the Secretary terminates an agreement for cause, an involuntary termination. Nothing in the Medicare statute authorizes MACs to make such determinations in either situation. And, nothing in the Medicare statutes allows the Secretary or CMS to delegate such responsibility to MACs.

Delegation to a federal sub-agency, such as CMS, or to other federal officers is generally permitted. However, delegation to a **non-government** entity is very different. To be valid, the latter type of delegation requires an affirmative showing of Congressional authorization. *See U.S. Telecom Ass’n v. F.C.C.*, 359 F.3d 554, 556 (D.C. Cir. 2004). No such express or affirmative authorization to subdelegate such responsibility is present in the Medicare statutes with respect to terminating Medicare provider agreements.

The Secretary cites *Agendia, Inc. v. Becerra*, 4 F.4th 896, 902 (9th Cir. 2021) to support his argument that MACs, including Novitas, may be delegated authority by Congress to act on behalf of the Secretary so long as they function subordinately to the Secretary. Doc. 12, page 26. However, *Agendia* is easily distinguished. In that case, the Court was addressing the constitutionality of Medicare Local Coverage Determinations (“LCDs”) issued by MACs under 42 U.S.C. § 1395kk-1(a)(4). There, unlike here, Congress had expressly delegated specific authority to MACs to enact such LCDs under 42 U.S.C. § 1395kk-1(a)(4). 4 F. 4th at 902-03. Here, there is no such express statutory authorization regarding the termination of provider agreements. As stated above, absent such express authority, MACs are prohibited from performing the functions Novitas performed here.

Under the APA, the Court is thus required to hold unlawful and set aside Novitas’ termination of DCMH’s provider agreement and Medicare enrollment because such action is *ultra vires*.

C. The Medicare Statutes Do Not Permit MACs to Deactivate a Provider’s Medicare Billing Privileges.

Nothing in the Medicare statutes authorizes or even discusses the “deactivation” of a provider’s billing privileges. The Secretary nevertheless amended 42 C.F.R. § 424.540, effective January 1, 2022, to add subsection (a)(7).

See 86 Fed. Reg. 62240 [November 9, 2021]. Notwithstanding the lack of express statutory authority, the amended 2022 regulation purportedly permits the deactivation of a provider’s billing privileges when the provider is “voluntarily withdrawing from Medicare.” And, it adds that the deactivation for this reason would be effective “the date on which the provider . . . voluntarily withdrew from Medicare.” 86 Fed. Reg. 62359 [November 9, 2021].

Nothing in the Medicare statute authorizes (1) “deactivations of billing privileges,” and/or (2) allows MACs to impose such “deactivations.” And, in any event, nothing in the record of the MAC’s determinations in this case contains any evidence of DCMH “voluntarily withdrawing from the Medicare Program” at any time. In fact, DCMH never did so. Statement, para. 12.

D. The Medicare Statute Does Not Authorize Terminations Based on the “Cessation of Business.”

Termination of provider agreements is statutorily authorized (and limited to) those cases in which a provider chooses to terminate such an agreement and those cases where the Secretary terminates an agreement after he determines that a provider has failed to comply with certain provisions and for other instances of good cause. *See* 42 U.S.C. § 1395cc(b). The statute says nothing about the “cessation of business.” Notwithstanding this lack of express statutory authority, the Secretary has enacted a regulation that includes the cessation of business as a

basis for terminating a provider “effective with the date on which it stopped providing services to the community.” 42 C.F.R. § 489.52(b)(3). Absent such express statutory authorization for this sanction, the Secretary may not impose it. *See American Bus Assn. v. Slater*, 231 F.3d 1, 2 (D.C. Cir. 2000), where the court concluded that the Department of Transportation lacked the statutory authority to impose money “damages” as sanctions against over-the-road bus operators that failed to provide accessible services to disabled passengers. “Congress has given the agency no authority to establish remedies in addition to those that are specified in the ADA.” The Court relied on 5 U.S.C. § 558(b) to confirm its decision. This reasoning is applicable here.

E. DCMH Did Not Voluntarily Terminate Its Provider Agreement.

According to the Secretary, DCMH voluntarily chose to stop providing inpatient services, which means that it no longer qualified as a hospital under the Medicare conditions of participation. And, the Secretary insists this was the case even though DCMH never notified the Secretary it was terminating its Medicare agreement. In reality, PA DOH forced DCMH to stop furnishing inpatient hospital services effective November 7, 2024. However, DCMH continued to provide outpatient services thereafter.

As pointed out above, in *Parkview*, a hospital informed the Secretary that it was going to stop providing inpatient hospital services effective June 18, 2015, but

would continue furnishing outpatient hospital services. The Secretary's ALJ determined that the cessation of inpatient services would violate the requirements for qualifying as a hospital and thus constitute an **involuntary** termination of its provider agreement. And, because such action constituted an involuntary termination, the Secretary was required to give the hospital a 15-day notice of such termination "before the termination would go into effect." This is how this matter should have been handled.

The Secretary cites four out-of-district decisions to support Novitas' decision. Doc. 12, pages 24-25. None is on point, including *Santiago v. Leavitt*, 2008 WL 4131524, at *4 (N.D. Tx. Sept. 3, 2008), where a home health agency's former owner had voluntarily discharged patients. The court dismissed the action because, among other reasons, the plaintiff was not the "provider" when the decision to terminate the provider was made and thus lacked standing. Similarly, the unpublished bankruptcy court decisions in *In re Center City Healthcare, LLC*, and *In re BR Healthcare Sols., LLC*, 2021 WL 4597761 (W.D. Tx. Oct. 5, 2021) did not involve Medicare jurisdiction issues. And, the Secretary's reliance on *Kaiser v. Blue Cross of Cal.*, 2006 WL 8448799 (D. Idaho, Sept. 22, 2006) is misplaced because it involved different jurisdictional provisions than those here and different causes of action. In any event, as shown above, DCMH did not voluntarily close its doors.

F. The Medicare Statute Expressly Prohibits the Retroactive Termination of a Medicare Provider Agreement or Enrollment.

The controlling statute, 42 U.S.C. § 1395cc(b)(3), expressly states that the “termination of an agreement . . . shall become effective on the same date and in the same manner as an exclusion from participation” in the federal healthcare programs, including Medicare, under 42 U.S.C. § 1320a-7(c). This latter provision requires **prior notice** to be given to the excluded entity and “shall be effective with respect to services furnished to an individual on or after the effective date of the exclusion.” Nothing in the statute or regulation permits a retroactive implementation of a termination.

Under the statute, 42 U.S.C. § 1395cc(b)(1), only if a provider of services gives notice to the Secretary and the public may it voluntarily withdraw from the Medicare. Under the Secretary’s regulation, 42 C.F.R. §489.52(a)(1), a provider must send CMS written notice of its intention to terminate its agreement. A provider may only request a retroactive termination date if no Medicare beneficiary received services after the requested date. 42 C.F.R. § 489.52(b). This was not the case here.

This same regulation (but not the statute) indicates that a “cessation” of business “is deemed to be a termination by the provider.” And, “cessation” is explained as when a provider “stopped providing services to the community.”

Even assuming that this regulation is authorized by the statute, it is undisputed here that DCMH continued providing Part B services to Medicare beneficiaries and others in the community long after November 7, 2022.

G. The Retroactive Implementation of the Termination and Deactivation Violates DCMH's Due Process Rights.

Obviously, there is a substantial difference between the impact of a **prospective and a retroactive** termination of DCMH's Medicare participation and billing privileges. Because Novitas imposed the termination and deactivation retroactively, DCMH is deprived of payment for services previously furnished to Medicare beneficiaries – services for which DCMH already incurred the substantial costs of delivering. Statement, para. 15.

In the present case, neither the Secretary nor Novitas afforded DCMH any **prior notice** of the actions imposed by Novitas on May 21, 2024, including the termination of its Medicare provider agreement and enrollment and the deactivation of its billing privileges retroactively to November 7, 2022. And, neither the Secretary nor Novitas provided DCMH with any meaningful opportunity to be heard – before or after it imposed its actions. Novitas gave DCMH only one shot (a written rebuttal) to challenge its decision, which was meaningless.

Making matters worse, Novitas mischaracterized its decision as a

deactivation of billing privileges, only, which does not constitute an appealable “initial determination,” and therefore deprived DCMH of its right to pursue the administrative appeal process applicable to the termination of Medicare participation under 42 U.S.C. § 1395cc(h) and 42 C.F.R. §§ 405.498 *et seq.*

The circumstances here are tantamount to, if not more egregious than, the imposition of a retroactive ban on Medicare admissions. And, in *Nassau Nursing Home v. Heckler*, 614 F. Supp. 1091 (E.D.N.Y. 1985), the court held that a pre-ban hearing was required at a minimum to satisfy due process. Because of the retroactive implementation of the actions imposed here, no pre-termination hearing will have been afforded DCMH, which constitutes a violation of due process.

Additionally, contrary to the clear language and intent of the Medicare statute, no meaningful post-termination hearing was afforded DCMH. Thus, its only recourse to correct the unlawful action in this case lies with this Court in light of Novitas’ decision treating its May 21, 2024 determination as allowing only a written rebuttal, which, in turn, denies DCMH the right to pursue the ordinary post-termination rights afforded Medicare providers.

Therefore, even if the Court were to conclude that DCMH was entitled to additional pre-termination rights, DCMH requests the Court to hold that DCMH should have been afforded the right to be heard through the multi-level post-termination appeal process required to be given to a terminated provider.

In this regard, this case is different from the situation in *Senior Life York, Inc. v. Azar, supra*, where the court held that the pre-deprivation opportunities given to the provider there to discuss the facts and circumstances alleged by CMS with CMS, **and** the post-deprivation rights to be heard, including the right to a hearing before CMS, available to the provider under 42 C.F.R. § 422.756(b), satisfied due process requirements. *See* 418 F. Supp. 3d at 67. These rights were not offered or given to DCMH in this case.

VI. CONCLUSION AND REMEDIES REQUIRED

For the above reasons, DCMH respectfully requests the Court to grant its motion for summary judgment and to hold that Novitas' May 21 and July 1, 2024 determinations are unlawful and must be set aside under 5 U.S.C. § 706(2)(B), (C), and (D), because Novitas (and thus the Secretary) has acted (1) contrary to constitutional right and power; (2) in excess of statutory jurisdiction, authority, limitation, and short of statutory right; and (3) without observance of the procedure required by law.

Dated: January 15, 2025

/s/ Patric Hooper

Kelly A. Carroll (PA Bar No. 312621)

David Vernon (DC Bar No. 1030537)

(admitted pro hac vice)

HOOPER, LUNDY &

BOOKMAN, P.C.

401 9th Street, NW, Suite 550

Washington, D.C. 20004

(202) 580-7712

kcarroll@hooperlundy.com

dvernon@hooperlundy.com

Patric Hooper (CA Bar No. 57343)

(admitted pro hac vice)

HOOPER, LUNDY &

BOOKMAN, P.C.

1875 Century Park East, Suite 1600

Los Angeles, CA 90067-2517

(310) 551-8111

phooper@hooperlundy.com

Attorneys for Plaintiff